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THE WEINBERG GROUP INC.

VIA COURIER

April 1, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93, and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product **Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension** 200 mg/28.5 mg and 400 mg/57 mg are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petition is submitted for a change in dosage form of the drug product from "Chewable Tablet" to "Tablets for Oral Suspension." The reference listed drug product is Augmentin® Chewable Tablets 200 mg (200 mg amoxicillin and 28.5 mg clavulanic acid as the potassium salt) and 400 mg (400 amoxicillin and 57 mg clavulanic acid as the potassium salt), manufactured by GlaxoSmithKline (GSK). Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension will be marketed in dosage strengths of 200 mg and 400 mg.[1] The drug, the route of administration and the recommendations for usage are the same as the listed drug product. The proposed product would differ only in dosage form from GSK's marketed product.

[1] The Petitioner's proposed products are Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension (200 mg amoxicillin and 28.5 mg clavulanate potassium; 400 mg amoxicillin and 57 mg clavulanate potassium).

The proposed drug product is expected to demonstrate bioequivalence to the 400 mg chewable tablet of the listed product; data will be submitted at a later date. Note that this petition follows the previous submission and subsequent withdrawal of the 200 mg/28.5 mg, 400 mg/57 mg dosage strengths of Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension from 02P-0406/CP1. Those two strengths were withdrawn from 02P-0406/CP1 at the request of the Agency to change the reference listed drug. We have complied with that request. Reference is made to the previous FDA review of that submission and to the conclusions of the Committee, as those conclusions will be applicable to the current petition.

B. Statement of Grounds

Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension are presented for administration by dispersing a single tablet in a specified amount of water.

The new dosage form is expected to offer a better alternative to the chewable tablets due to the ease of administration to patients who have difficulty chewing and swallowing a chewable tablet, and for people who prefer a liquid dosage form.

The proposed product will differ only in dosage form. The indications, strength, route of administration, intended patient population and recommendations for usage will remain the same as the GSK-marketed products; therefore, there will be no difference in the safety and efficacy of the Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension.

The package insert for GSK's Augmentin® Chewable Tablets (Attachment 1) is provided, as well as the draft package insert of the proposed Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension (Attachment 2).

C. Pediatric Use Information

In December of 2003, Congress passed the Pediatric Research Equity Act (PREA) of 2003 that amended the Federal Food, Drug and Cosmetic Act (The Act) to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such study would provide beneficial health data for that patient population. Requirements are outlined in the PREA and with concepts provided in the Draft Guidance for Industry [Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)), dated November 2000].

Reference is also made to the Agency's communication for the previous petition dated February 3, 2004 (02P-0406, Let 1) recommending submission of a letter requesting a pediatric waiver in accordance with the provisions of Section 2 of PREA, if applicable.

Section 505B(a)(4)(A)(iii) of The Act (as amended by PREA) provides a provision for a waiver from providing assessments of pediatric use of a drug if:

(iii) the drug or biological product --

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies of Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension for all age groups be granted for this petition.

The Reference Listed Drug Augmentin® Chewable Tablets (GSK) is, according to the approved labeling, recommended for use in the treatment of infections caused by susceptible strains of certain organisms in conditions such as lower respiratory tract infections and otitis media. The petitioner's proposed product, Tablets for Oral Suspension, form an oral suspension on dispersion of the exact dosage in the Reference Listed Drug chewable tablets. This petition simply requests a change in dosage form from "Chewable Tablets" to "Tablets for Oral Suspension."

The proposed product, Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension, is designed to provide a more convenient dosage form of amoxicillin and clavulanate potassium for those patients who have difficulty chewing and swallowing chewable tablets or who prefer a liquid dosage form. This benefit, while not excluding pediatric patients, is directed to the adult population. The petitioner believes that Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension does not represent a meaningful therapeutic benefit over existing antibiotic therapies or over the Reference Listed Drug, Augmentin® Chewable Tablets for the pediatric patient population.

Furthermore, additional clinical studies in the pediatric population with the petitioner's tablets for oral suspension would not offer meaningful data, nor would they demonstrate a therapeutic benefit over Augmentin® Chewable Tablets in the pediatric patient population for which it is indicated. As stated in the product labeling for Augmentin® Chewable Tablets, pediatric studies have been conducted with the Reference Listed Drug, and the product labeling contains adequate dosing and administration information for the pediatric population. The label for Augmentin® Chewable Tablets specifies doses for the pediatric population from neonates to 3 months of age, and for 3 months and older (see Attachment 1). The planned labeling for Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension will specify the same dose information (see Attachment 2).

Further, a bioequivalence study is planned comparing the Reference Listed Drug with Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension and a product demonstrated to be bioequivalent in adults is accepted to be bioequivalent in a pediatric population. Therefore, additional studies would be redundant and unnecessary.

The planned bioequivalence study will compare Augmentin® 400 Chewable Tablets (400 amoxicillin and 57 mg clavulanic acid as the potassium salt) with Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension (400 amoxicillin and 57 mg clavulanic acid as the potassium salt) in adult volunteers. The petitioner believes that the bioequivalence study conducted on adults should be adequate to demonstrate bioequivalence in children.

For the reasons stated above and consistent with the provisions of the Pediatric Research Equity Act of 2003, the petitioner respectfully requests that this waiver be granted.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Nicholas Fleischer

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Vice President
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NMF/kh

Enclosure

cc Gary Buehler, Director, Office of Generic Drugs